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EXAMINER	
KREMER, MATTHEW J	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,895	PORGES ET AL.	
	Examiner	Art Unit	
	Matthew J Kremer	3736	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 11122003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 8-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 8-9 place limitations on the monitor but places no further structural limitation on the claimed invention of the sensor.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,675,031 to Porges et al. (Porges). In regard to claim 1, claim 1 of Porges claims a

system that includes a sensor "for sensing at least one physiological characteristic of a patient, the sensor being connectable to a monitor that estimates a physiological characteristic from signals detected by the sensor, the sensor comprising: a detector for detecting the signals from the patient which are indicative of the physiological characteristic; a memory connected with the sensor...and said memory being configured to store data defining at least one sensor signal specification boundary for the detected signals, the sensor signal specification boundary being indicative of a quality of the signals and an accuracy of the physiological characteristic estimated from the signals by the monitor; and means for providing access to the memory to allow transmission of the data defining the at least one sensor boundary to the monitor." Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of Porges claims a system with a sensor, which is narrower in scope than the present application which includes just the sensor. Claim 1 of Porges meets all the limitations set out in claim 1 of the present application and it would be obvious that the sensor of claim 1 of the present invention is encompassed in the sensor of claim 1 of Porges.

In regard to claim 2, claim 2 of Porges claims "wherein the sensor signal specification boundary includes limits for an AC modulation component of the signals." In regard to claim 3, claim 3 of Porges claims "wherein the sensor signal specification boundary includes limits for a DC component of the signals." In regard to claim 4, claim 4 of Porges claims "wherein the monitor computes...values...from the signals, wherein the sensor signal specification boundary constitutes limits on the AC and DC

components of the calculated values, and wherein the AC and DC components are dependent on either a physiological status of the patient, sensor type, or sensor location." In regard to claim 5, claim 5 of Porges claims "wherein the signals detected from the patient include first and second sets of signals derived from detected light scattered from the patient, the light having first and second wavelengths, the signals derived from detected light each having an AC modulation component and a DC component, and the sensor signal specification boundary including limits on the AC and DC components." In regard to claim 6, claim 6 of Porges claims "wherein the signals derived from detected light are indicative of an arterial oxygen saturation of the patient." In regard to claim 7, claim 7 of Porges claim "wherein the memory comprises a digital memory configured to store a digital representation of the at least one sensor signal specification boundary, and wherein the physiological characteristic is arterial oxygen saturation." In regard to claim 8, claim 1 of Porges claims "wherein the monitor determines to display or not display the estimate of the physiological characteristic based on the signals and their relationship relative to a plurality of sensor signal specification boundaries and to a plurality of monitor boundaries preprogrammed into the monitor."

In regard to claim 9, claim 8 of Porges claims claims a system that includes a sensor "for sensing at least one physiological characteristic of a patient, the sensor being connectable to a monitor that estimates a physiological characteristic from signals detected by the sensor, the sensor comprising: a detector for detecting the signals from the patient which are indicative of the physiological characteristic; a memory connected

with the sensor...and said memory being configured to store data defining at least one sensor signal specification boundary for the detected signals, the sensor signal specification boundary being indicative of a quality of the signals and an accuracy of the physiological characteristic estimated from the signals by the monitor; and means for providing access to the memory to allow transmission of the data defining the at least one sensor boundary to the monitor, wherein the monitor displays an indication of the quality of the signals based on their relationship relative to a plurality of sensor signal specification boundaries and to a plurality of monitor boundaries preprogrammed into the monitor." Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 8 of Porges claims a system with a sensor, which is narrower in scope than the present application which includes just the sensor. Claim 8 of Porges meets all the limitations set out in claim 9 of the present application and it would be obvious that the sensor of claim 9 of the present invention is encompassed in the sensor of claim 8 of Porges.

In regard to claim 10, claim 9 of Porges claims a "monitor for providing an indication of an accuracy of an estimated physiological condition of a patient, the monitor being connectable to a sensor that detects signals indicative of at least one physiological characteristic of the patient, the monitor comprising: at least one receiving circuit configured to receive the signals indicative of the at least one physiological characteristic from the sensor and data defining at least one sensor signal specification boundary for the detected signals from the sensor, the sensor signal specification boundary being indicative of a quality of the signals detected by the sensor and an

accuracy of the physiological characteristic estimated from the detected signals; at least one processing circuit configured to estimate the physiological condition of the patient based on the received signals, compare the received signals against the at least one sensor boundary, and generate the indication of the accuracy of the estimated physiological condition; and means for providing the indication of the accuracy of the estimated physiological condition to a user of the monitor." Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 9 of Porges claims a monitor which is narrower in scope than the monitor of claim 10 of the present invention. Claim 9 of Porges meets all the limitations set out in claim 10 of the present application and it would be obvious that the monitor of claim 10 of the present invention is actually the monitor of claim 9 of the present invention.

In regard to claim 11, claim 10 of Porges claims "wherein the at least one sensor boundary is indicative of a transition between a signal regime considered normal for the sensor in its usual application and a signal regime considered to be abnormal." In regard to claim 12, claim 11 of Porges claims "wherein the at least one processing circuit is further configured to determine whether the received signals are within the normal regime or the abnormal regime." In regard to claim 13, claim 12 of Porges claims "wherein the at least one processing circuit is further configured to compute an indication of whether the sensor is likely to be applied to the patient or has partially or entirely came off the patient."

In regard to claim 14, claim 13 of Porges claims a "physiological monitoring system comprising: a sensor that includes a detector for detecting signals from a patient

which are indicative of at least one physiological characteristic of the patient; a memory connected with the sensor...and said memory being configured to store data defining at least one sensor boundary for the detected signals; and a monitor coupled to the sensor and the memory, the monitor includes at least one receiving circuit configured to receive the detected signals and the data defining the at least one sensor boundary...at least one processing circuit configured to estimate a physiological condition of the patient based on the received signals, compare the received signals against the at least one sensor boundary, and generate an indication of an accuracy of the estimated physiological condition, and means for providing the indication of the accuracy to a user of the system..." Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 13 of Porges claims a monitoring system which is narrower in scope than the monitor of claim 14 of the present invention. Claim 13 of Porges meets all the limitations set out in claim 14 of the present application and it would be obvious that the monitoring system of claim 14 of the present invention is actually the monitoring system of claim 13 of Porges.

In regard to claim 15, claim 14 of Porges claims a system including a sensor "for sensing at least one physiological characteristic of a patient, the sensor being connectable to a monitor that estimates the physiological characteristic from signals detected by the sensor, the sensor comprising: a detector for detecting the signals from the patient which are indicative of the physiological characteristic; a memory connected with the sensor...said memory being configured to store data defining at least one sensor signal specification boundary for the detected signals, the sensor signal

specification boundary being indicative of a transition between a signal regime considered normal for the sensor in its usual application, and a signal regime considered to be abnormal...means for providing access to the memory to allow transmission of the data defining the at least one sensor boundary to the monitor..." Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 15 of Porges claims a system with a sensor, which is narrower in scope than the present application which includes just the sensor. Claim 14 of Porges meets all the limitations set out in claim 15 of the present application and it would be obvious that the sensor of claim 15 of the present invention is encompassed in the sensor of claim 14 of Porges.

In regard to claim 16, claim 15 of Porges claims "in which said sensor signal specification boundary is characteristic of a model of the sensor." In regard to claim 17, claim 16 of Porges claim "in which said boundary is characteristic of individual components used in making the sensor." In regard to claim 18, claim 17 of Porges claims a system with the sensor and "a pulse oximetry monitor having means to determine whether the signals are within said normal regime or said abnormal regime; and means for informing a user of the system as to whether the signal is normal or abnormal." In regard to claim 19, claim 18 of Porges claims "wherein said means for informing the user is an alarm that is triggered when the signal moves from said normal regime to said abnormal regime." In regard to claim 20, claim 19 of Porges claims "wherein said normal regime is one in which the sensor is likely to be properly applied to

the patient and said abnormal regime is one in which the sensor may have partially or entirely come off the patient."

In regard to claim 21, claim 20 of Porges claims a "pulse oximetry system comprising: a sensor for sensing at least one physiological characteristic of a patient, the sensor being connectable to a monitor that estimates the physiological characteristic from signals detected by the sensor, the sensor comprising a detector for detecting the signals from the patient which are indicative of the physiological characteristic; a memory connected with the sensor...said memory being configured to store data defining at least one sensor signal specification boundary for the detected signals, the sensor signal specification boundary being indicative of a transition between a signal regime considered normal for the sensor in its usual application, and a signal regime considered to be abnormal; and means for providing access to the memory to allow transmission of the data defining the at least one sensor boundary to the monitor, and the system further comprising a pulse oximetry monitor that includes means to determine whether the signals are within said normal regime or said abnormal regime, said normal regime being one in which the sensor is likely to be properly applied to the patient and said abnormal regime being one in which the sensor may have partially or entirely come off the patient, means to compute other measures which indicate a probability that the sensor has come off the patient...and means to combine mathematically indication of whether the signals are within said normal regime or said abnormal regime and the other measures so as to compute a net probability that the sensor has come off the patient. Although the conflicting claims are not identical, they

are not patentably distinct from each other because claim 20 of Porges claims a system, which is narrower in scope than claim 21 of the present application. Claim 20 of Porges meets all the limitations set out in claim 21 of the present application and it would be obvious that the system of claim 21 of the present invention is actually the system of claim 20 of Porges.

In regard to claim 22, claim 20 of Porges claims a "pulse oximetry system comprising: a sensor for sensing at least one physiological characteristic of a patient, the sensor being connectable to a monitor that estimates the physiological characteristic from signals detected by the sensor, the sensor comprising a detector for detecting the signals from the patient which are indicative of the physiological characteristic; a memory connected with the sensor...said memory being configured to store data defining at least one sensor signal specification boundary for the detected signals, the sensor signal specification boundary being indicative of a transition between a signal regime considered normal for the sensor in its usual application, and a signal regime considered to be abnormal; and means for providing access to the memory to allow transmission of the data defining the at least one sensor boundary to the monitor, and the system further comprising a pulse oximetry monitor that includes means to determine whether the signals are within said normal regime or said abnormal regime, said normal regime being one in which the sensor is likely to be properly applied to the patient and said abnormal regime being one in which the sensor may have partially or entirely come off the patient, means to compute other measures which indicate a probability that the sensor has come off the patient...and means to combine

mathematically indication of whether the signals are within said normal regime or said abnormal regime and the other measures so as to compute a net probability that the sensor has come off the patient.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,846,190 to Woehrle (cited by the Applicant) in view of U.S. Patent 5,987,343 to Kinast (cited by the Applicant), and further in view of U.S. Patent 6,104,938 to Huiku et al. (cited by the Applicant). Woehrle teaches a pulse oximeter system with a sensor that has a detector 6 and two light emitting diodes. (column 7, lines 23-37 of Woehrle). One processing channel examines an ambient light signal which is used to determine a useful-to-noise-signal ratio (NSV). The NSV is a measurement of signal quality, which is compared to a threshold that determines if an alarm is activated. Woehrle discloses the calculation of the NSV which is used to determine if the sensor has fallen off the patient by activating an alarm if the value is above a certain threshold. (column 9, lines 26 to column 10, line 9 of Woehrle) Woehrle does not teach that the threshold is stored in a sensor memory. It is well

known in the art to attach a memory unit to an oximeter sensor. (Abstract of Kinast). Kinast teaches that it is desirable to store several parameters in sensor memory such as LED intensity, date of manufacture, sensor type, number of patient uses, and record cumulative hours of operation. Such information is used to determine whether the sensor has worn out and what are the operating parameters of the sensor. Other information can also include the calibrated data for a particular sensor. (column 8, lines 32-43 of Huiku et al.). The storage of calibrated data in the sensor allows more accurate determinations based on the calibrations of the sensor without the need to store a large number of various calibrations in the oximeter. The storage of calibrated data also allows for various hemoglobin components to be analyzed. (column 5, lines 33-52 of Huiku et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Woehrle to include a sensor memory as disclosed by Kinast and Huiku et al. since the storage of variables, such as LED intensity, date of manufacture, sensor type, number of patient uses, record cumulative hours of operation, and the calibrated data for calculations, allows for more accurate determinations without the need to store a large number of calibrations in the oximeter, allows for the determination of the operating parameters of the sensor, allows for the determination of whether the sensor has worn out, and allows for the analysis of various hemoglobin components. In the combination, the reason for the NSV threshold is to determine whether the operation of the sensor is within a particular operating region. The NSV threshold is a function of the amplitude of the measurement signal and the amount of possible ambient light. However, the amplitude

of the measurement signal and the amount of possible ambient light depends on such factors as LED intensity, type of sensor, and the calibration data. The inference to make from this is that the NSV threshold would be placed in the sensor memory since the factors that determine the threshold are stored in the sensor memory. To place the NSV threshold in the oximeter would require storing calibrated data from various sensors in the oximeter which is something the sensor memory is used to avoid. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include the NSV threshold in the sensor memory since the factors that determine the threshold are stored in the sensor memory. The sensor memory storing the NSV threshold is considered to be the memory associated with the sensor. The combination teaches a means for providing access to the memory. (The line between memory 4 and reader 14 in Fig. 6 of Huiku). In regard to claims 1, 7, 10, and 14, Woehrle implies that the accuracy of the signal quality is an indication of the accuracy of the estimated physiological condition. (column 2, lines 28-59 of Woehrle). In regard to claims 2-4, the NSV threshold includes a boundary of a mean amplitude (DC component) or a peak amplitude (AC component) or both of the measurement signal (column 4, lines 41-67 of Woehrle). In regard to claim 5, red and infrared measurements are used. (column 3, lines 50-53 of Woehrle). In regard to claims 6-7, oxygen saturation is determined. (Abstract of Woehrle). In regard to claim 8, the limitation "wherein the monitor determines to display or not display the estimate of the physiological characteristic based on the signals and their relationship relative to a plurality of sensor signal specification boundaries and to a plurality of

monitor boundaries preprogrammed into the monitor" does not add any structural limitation to the claimed sensor and was not given any patentable weight. In regard to claim 9, the limitation "wherein the monitor displays an indication of the quality of the signals based on their relationship relative to a plurality of sensor signal specification boundaries and to a plurality of monitor boundaries preprogrammed into the monitor" does not add any structural limitation to the sensor and was not given any patentable weight. In regard to claims 10-13, a monitor is disclosed that includes receiving and processing circuits (Fig. 1 of Woehrle) and an alarm. (column 4, lines 6-9 of Woehrle). In regard to claims 15-17, the signal specification boundary is the NSV threshold which depends upon the amplitude of the measurement signal and the amount of possible ambient light which are functions of LED intensity, type of sensor, and the calibration data. In regard to claims 18-20, an alarm is disclosed. (column 4, lines 6-9 of Woehrle).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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